

## **REMARKS**

### **I. STATUS OF CLAIMS**

The pending Office Action addresses and rejects claims 1-11. Reconsideration of the pending rejections is respectfully requested in view of the following remarks.

### **II. AMENDMENTS TO THE CLAIMS**

Claim 11 is amended to correct inadvertent antecedent basis errors. Entry of this amendment after final is proper because it places the application in condition for allowance, as discussed below, or at least in better condition for appeal. No new matter is added.

### **III. GROUNDS OF REJECTION**

Claims 1-11 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,632,748 of Beck, Jr. et al. ("Beck") in view of U.S. Patent No. 6,325,804 of Wenstrom, Jr. et al. ("Wenstrom"); or in the alternative in view of PCT Patent Application No. WO 96/00592 of Agrawal ("Agrawal").

Independent claim 1 recites, in relevant part, providing a biodegradable, composite interference screw including a copolymer of poly (lactic acid) and poly(glycolic acid), and a bioceramic, inserting the biodegradable screw into a femoral bone tunnel, and rotating the interference screw such that the screw is substantially contained within the femoral bone tunnel.

The Examiner alleges that Beck discloses the claimed invention except that the biodegradable material comprises a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates. The Examiner thus relies on Wenstrom, or in the alternative, Agrawal, for these features.

### **IV. SUMMARY OF THE PRIOR ART**

#### ***A. General Description of Wenstrom***

Wenstrom generally discloses a bone plug inserted into and fixed to a femoral bone tunnel using an adhesive such as cement or bone glue. See Wenstrom, e.g., Abstract and col. 2, lines

25-59. The bone plug can be natural, or it can be artificial and made from a variety of materials “including polylactic acid and polyglycolic acid as well as bioceramics such as tricalcium phosphate, calcium phosphate, tetracalcium phosphate and hydroxyapatite, and any copolymers, mixtures or blends thereof, and the like and equivalents thereof.” *Id.*, col. 6, lines 44-50. To insert the bone plug into the femoral bone tunnel, a suture is mounted to the bone plug and threaded through previously drilled tibial and femoral bone tunnels. See *Id.*, col. 5, lines 39-47. The surgeon then pulls the suture to slide the bone plug through the tibial tunnel and into the femoral tunnel. See *Id.*, col. 5, lines 47-54. Adhesive is introduced into the femoral tunnel distal to the bone plug, and the surgeon again pulls the suture to distally slide the bone plug into desired position in the femoral bone tunnel and to spread the adhesive. See *Id.*, col. 5, line 54 to col. 6, line 4. The adhesive cures, thereby securing the bone plug within the femoral tunnel. See *Id.*

#### **B. General Description of Agrawal**

Agrawal generally discloses a bone fixation plate that mounts onto a bone surface to support the bone. See Agrawal, e.g., Abstract and p. 4, lines 30-34. The bone plate includes multiple, alternating layers of a biodegradable polymer layer and a biodegradable reinforcement structure. See *Id.*, e.g., Abstract, p. 1, lines 10-17, and p. 9, line 35 to p. 10, line 12. The biodegradable polymer layer can be formed from a variety of materials, such as 100% polylactic acid or a 50%-50% copolymer of polylactic acid and polyglycolic acid. See *Id.*, e.g., p. 16, lines 3-22. The biodegradable reinforcement structure can also be made from a variety of materials, such as ceramic fibers or beads, or alternatively, polylactic acid and/or polyglycolic acid. See *Id.*, e.g., p. 8, lines 12-29 and p. 9, lines 29-33.

#### **V. ARGUMENTS**

As noted above, the Examiner relies on the teachings of Wenstrom or Agrawal to disclose the claimed materials, and argues that it would have been obvious to use these materials in the interference screw and method disclosed by Beck. Applicant continues to disagree. As explained in detail below, a person of ordinary skill in the art would not have modified Beck in view of either Wenstrom or Agrawal at least because Wenstrom and Agrawal do not teach or suggest that the claimed combination of materials would be suitable for the intended use, and the claimed invention provides unexpected results not available in the prior art. The Examiner has failed to provide any

reasons for making the proposed modification, and instead the Examiner's rejection is the result of an improper reliance on hindsight.

**A. *Wenstrom and Agrawal Do Not Teach or Suggest That the Claimed Combination of Materials Would Be Suitable for the Intended Use***

The combination of a bioceramic and a polymer including polylactic acid and polyglycolic acid was not known to be suitable for the intended use of an interference screw that is inserted into a femoral bone tunnel and rotated, and if anything was known to be unsuitable. One of ordinary skill in the art would thus not have selected the claimed combination.

The general intended use of the claimed combination of materials is to form a biodegradable interference screw for use in a method of replacing an anterior cruciate ligament in a knee. See, e.g., Application, p. 8, lines 22-27. As discussed in the previously submitted §1.132 Declaration of Lisa Donnelly (the "Declaration"), it was known at the time of Applicant's invention that the claimed materials were not well suited for use in bone anchors. See Declaration, par. 6. In particular, it was known that bone screws made from polylactic acid tended to persist in the body for long periods of time, thereby preventing bone ingrowth. See *Id.* It was also known that using other biodegradable polymers and copolymers of lactic acid resulted in premature mechanical failure of the screw due to bone regeneration proceeding at a slower rate than resorption of the polymers. See *Id.* Furthermore, it was known that bioabsorbable interference screws composed of a biodegradable polymer and a bioceramic posed problems of brittleness including fracture of screws as they were driven into bone. See *Id.*, par. 8.

The Examiner relies on *In re Leshin*, 277 F.2d 197 (C.C.P.A. 1960) on page 3 of the Office Action to support his argument regarding Wenstrom that selection of known materials on the basis of suitability for the intended use would have been obvious. The Examiner further argues on pages 5-6 of the Office Action that Wenstrom is cited for its teaching of "an implant." However, Wenstrom is entirely directed to a bone plug that slides through tibial and femoral tunnels until being fixed within the femoral tunnel using an adhesive. Disclosure of a smooth, slidable bone plug formed from a bioceramic and a copolymer of polylactic acid and polyglycolic acid does not provide teaching or suggestion for an interference screw formed of the claimed materials. Wenstrom in the specification's Background actually teaches away from using an interference

screw by discussing “traditional” attachments devices such as “staples, sutures, and bone screws” and the need for an alternative, e.g., the invention’s bone plug, to these “traditional” attachments devices. Wenstrom, col. 1, line 31 to col. 2, line 23. Wenstrom is merely directed to a *bone plug* that is pulled, not *rotated* as required by claim 1, to be contained within a femoral bone tunnel. Different forces are exerted for pulling and for rotating, and as discussed further below, the claimed combination of a biodegradable polymer and a bioceramic were specifically known to be unsuitable materials for an interference screw that is rotated to be contained in a bone tunnel.

Regarding Agrawal, on pages 3-4 of the Office Action the Examiner states that Agrawal discloses a bioceramic and a copolymer of polylactic acid and polyglycolic acid for a screw because screws are mentioned along with plates in the specification’s Background. The Examiner further argues on pages 5-6 of the Office Action that Agrawal is cited for its teaching of “an *implant*.” However, even if Agrawal discloses a bone fixation plate formed from a bioceramic and a copolymer of polylactic acid and polyglycolic acid, Agrawal is not concerned with any medical device inserted into a bone tunnel, much less an interference screw rotated therein. Rather, Agrawal’s invention is entirely directed to *bone plates* composed of multiple layers of *stacked* materials to give the plate enhanced load-bearing strength. No mention of *screws* are contained within the description of the invention (except in relation to conventional screws inserted through holes in a bone plate according to the invention to attach the bone plate to bone). Such plates are merely placed on a bone surface and are not inserted into a bone tunnel at all, much less rotated to be contained therein.

Thus, the claimed combination of materials was not known as disclosed in Wenstrom or Agrawal to be suitable for the intended use. Accordingly, the Examiner’s assertion that it was within the general skill of a worker in the art to select the materials for an interference screw, without any evidence that the combination was suitable for the intended use, is not enough to establish a prima facie case of obviousness, particularly in light of the materials being known in the prior art as being unsuitable for an interference screw.

***B. The Claimed Invention Provides Unexpected Results Not Available in the Prior Art***

Claim 1 is further patentable over Beck, Wenstrom, and Agrawal because the claimed

subject matter provides unexpected results over Beck, Wenstrom, and Agrawal, as well as over other prior art. The Declaration presents a number of statements indicating several unexpected results of the claimed invention that are not available in Beck, Wenstrom, and Agrawal or elsewhere in the prior art.

1. Prior Art Interference Screws Comprising a Copolymer Were Inadequate

Interference screws made from biodegradable polymers such as polylactic acid were known at the time of the invention. However, as the Declaration indicates, screws “made from polylactic acid tend to persist in the body for very long periods of time thereby preventing the desired bone in growth.” Declaration, par. 6. Screws made from other polymers or copolymers suffered from the problem “that the bone regeneration proceeded at a much slower rate than the rate of [screw] resorption. This would result in premature failure of the screw and a resulting pull out of the graft end from the femoral tunnel.” *Id.* Accordingly, the success of the claimed method of replacing an anterior cruciate ligament in a knee that includes providing a biodegradable interference screw comprising a biodegradable polymer, with the polymer including a copolymer of poly(lactic acid) and poly(glycolic acid) and a bioceramic, yields an unexpected result over the prior art.

2. Bioceramics Are Brittle

Generally, an interference screw fixes a graft in place in a bone tunnel and therefore “must be capable of withstanding the forces generated when the screw is threaded into the bone tunnel without fracturing or otherwise failing.” *Id.*, par. 8. As indicated in the Declaration, “the bioceramics described and claimed in the pending patent application are brittle materials and therefore not normally suitable for load bearing.” *Id.* Although bioceramics were known materials before the Applicant’s claimed invention, an interference screw comprising a bioceramic would be expected to be too brittle to withstand being screwed in a bone tunnel and holding a graft within the tunnel to promote proper in growth. Neither Wenstrom nor Agrawal provide any teaching or suggestion otherwise because, as discussed above, neither disclose an interference screw formed of the claimed materials nor does either disclose any medical device, much less an interference screw, inserted into in a femoral bone tunnel and rotated. Accordingly, the success of the claimed method of replacing an anterior cruciate ligament in a knee that includes providing a biodegradable

interference screw formed by the claimed materials, and rotating the screw such that the screw is substantially contained within the femoral bone tunnel yields an unexpected result over the prior art.

3. Applicant's Claimed Invention Achieves Unexpected Results Over the Prior Art

The Examiner argues on page 6 of the Office Action that the results of the claimed invention cannot be unexpected because "the prior art discloses the use of the claimed material for an implant and for an implant in a bone tunnel and subject to shearing forces." (Emphasis added.) However, as mentioned above in Section V.A, Wenstrom and Agrawal respectively concern bone plugs and bone plates, which are different from and subject to different forces than the interference screw recited in claim 1. As discussed in the Declaration, "extensive experimentation" was required to overcome the incompatible properties of the materials used to produce the interference screw including the claimed combination of materials that form a composite material. *Id.*, par. 9. At the time the invention was made, it was known in the art that the claimed combination of materials were "inherently incompatible" and "notoriously difficult to handle and process even when used separately (i.e. not as composites)." *Id.* Moreover, it was known that "the physical and chemical properties of the materials required careful handling during manufacturing to avoid negative impact on the properties of the composite." *Id.* Extensive experimentation was required to formulate a process that overcame the inherently incompatible properties of the materials to produce an appropriate composite for use in the claimed method in which an interference screw formed of a bioceramic and a polymer including polylactic and polyglycolic acids is inserted into a bone tunnel and rotated therein. *Id.* Accordingly, one of ordinary skill in the art would not have selected the claimed materials for use in the claimed method simply given Beck and the disclosure of a bioceramic and polylactic and polyglycolic acids in Wenstrom and Agrawal in the context of other medical devices that cannot be used as claimed.

4. Interference Screws Subsequent to the Applicant's Claimed Invention and Comprising a Copolymer and a Bioceramic Were Inadequate

Even following Applicant's extensive experimentation and claimed invention, interference screws formed of the claimed materials were ineffective. As indicated in the Declaration, interference screws disclosed in a paper by Chadwick A. Smith, M.D., published after the filing date

of the instant application, comprised a polymer including a copolymer and a bioceramic. See *Id.*, par. 8. However, the interference screws were inadequate because they “fractured as they were driven into the femoral tunnel,” and the method of insertion had to be modified. *Id.* Accordingly, the success of the claimed method of replacing an anterior cruciate ligament in a knee that includes providing a biodegradable interference screw comprising a biodegradable polymer, with the polymer including a copolymer and a bioceramic, yields an unexpected result over art known subsequent to the claimed invention and hence also over the prior art.

The Examiner provides no reasoning or even an assertion that Beck, Wenstrom, and Agrawal, alone or in any combination, achieves the same unexpected results of the claimed invention, much less that a person of ordinary skill in the art would know to focus on the claimed materials, particularly when Beck does not disclose the materials and when the materials were known to be ineffective for an interference screw rotated into a bone tunnel. None of Beck, Wenstrom, and Agrawal provide any such direction or teach the claimed invention, thereby failing to establish the obviousness of claim 1.

**C. *The Examiner’s Rejection is Improperly Based on Hindsight***

To make a prima facie showing of obviousness of a claimed invention in light of a given reference, the Examiner should “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l Corp. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Where no such explanation is given, as is the case here, improper use of hindsight can be inferred.

Here, the Office Action implausibly suggests forming an interference screw from a copolymer and a bioceramic combination of materials, blindly, with no reason to do so and no prospect for success (unless of course, one has Applicant’s disclosure in hand). Under *KSR*, that does not establish obviousness.

Accordingly, claim 1, as well as claims 2-11 which depend therefrom, distinguish over Beck, Wenstrom, and Agrawal, alone or in any combination, and represent allowable subject matter.

## **VI. Conclusion**

Applicant submits that all claims are in condition for allowance for at least the reasons discussed above, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

No extension of time is believed to be due with this filing. In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

No fee is believed to be due with this filing. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22956-743.

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Respectfully submitted,

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